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EXAMINER

NGUYEN, CAMTU TRAN

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 9/9/2009. Claims 1, 4-13, and 16 have been amended. Claims 19-25 have been cancelled. Claims 26-34 are newly added.

Response to Arguments

The 112, 1st paragraph rejection has been withdrawn in view of applicant's response.

Applicant remarked that the Gobby/Bacich, applied in the previous Office Action does not disclose **a tip shaped to be inserted into an endometrial lining of the subject**.

In response, since applicant's claims do not positively recite the tip is inserted into an endometrial lining of the subject and that the claims do not specify the shape of the tip, it is the Examiner's position to interpret applicant's claims as shown in Figures 4 & 5 of the Bacich reference where they illustrates the tip of catheter body (13, 13a) is shaped to be inserted into an endometrial lining and even capable of being inserted into an endometrial lining of the subject.

Applicant remarked that the Gobby/Bacich applied in the previous Office Action do not disclose **the tip comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject**.

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In response, claim 1 does not explicitly recite a specific material of tip that would render such rigidity & flexibility. Both the Gobby & the Bacich references are catheter devices of the same intended purposes, to assist embryo transfer procedure. It is inescapable that their catheter devices are of sufficient rigidity & sufficient flexibility.

The Gobby/Bacich rejection is remained, at least for the reasons presented above.

The claims, as amended, have been carefully considered but are rejected as follows.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show angle γ as described in the specification, paragraph 0029.

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement

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Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30 and 33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

When claim(s) recite(s) a device/apparatus with elements being "attached to" subject matter that is naturally occurring in nature, such recitation makes the claim(s) non-statutory.

In claims 30 & 33, the recitation **an embryo in the distal portion**.

These recitations positively claim non-statutory subject matter and it must be deleted or incorporated as a functional recitation in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11, 28 & 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claims 1 & 11 recite the tip **is shaped to be inserted into an endometrial lining of the subject**, such recitation is not supported by the specification.

Specifically, claims 28 & 32 reciting **the tip comprises a cutting tool**, such recitation is not supported by the specification. According to paragraph 0029, the last sentence therein provides disclosure for the tip (35) may be beveled in a direction opposite angle γ to **yield** a more refined cutting tool.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over by (U.S. Patent No. 4,474,576) and further in view of Bacich (U.S. Patent No. 5472419).

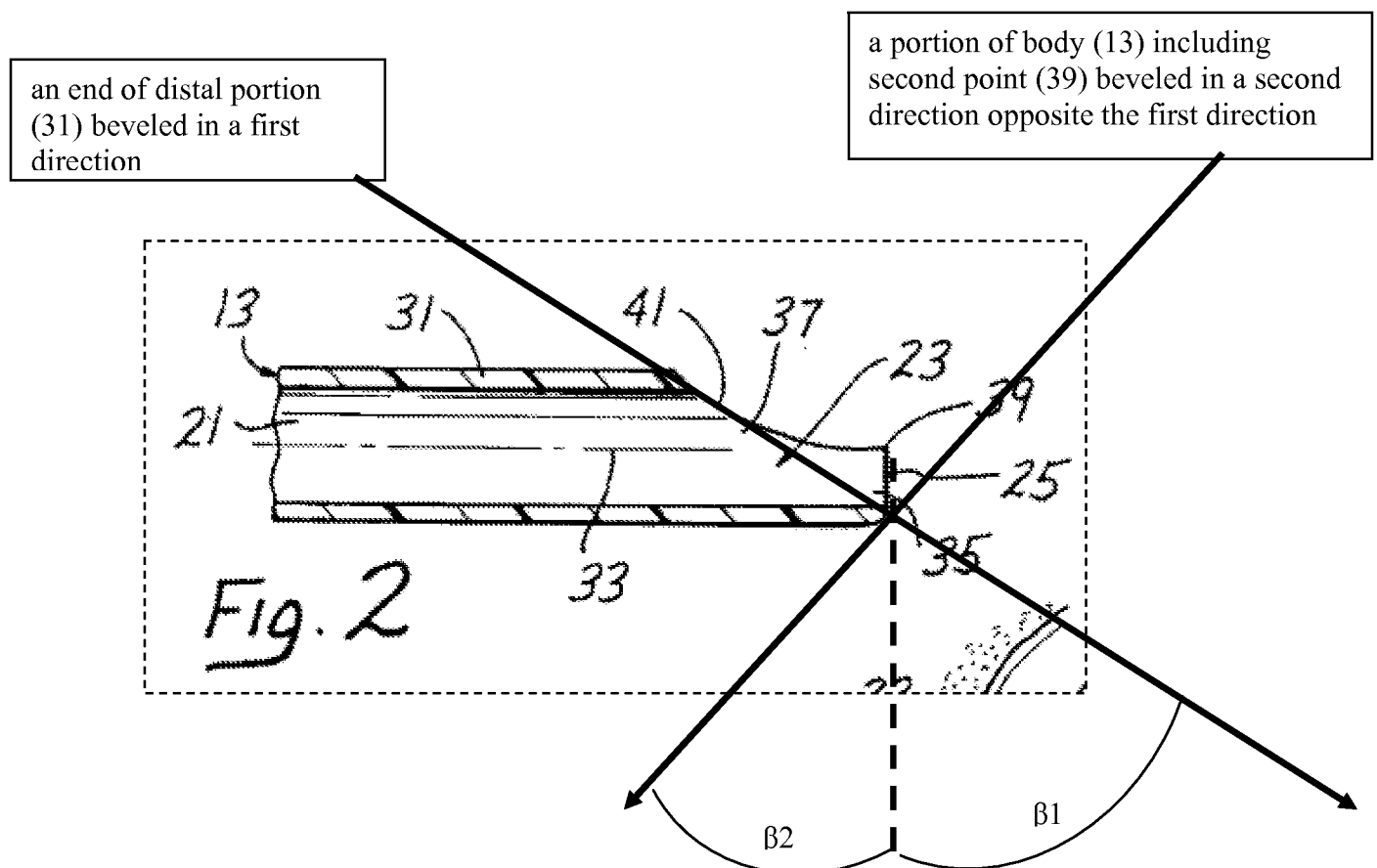
Gobby discloses an artificial insemination a delivery member (30) comprising a delivery section (51), a storage section (53), and a passage through both sections (51, 53), the delivery member (30) defines a first axis of symmetry throughout the passage. Figure

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2 illustrating a distal portion of the delivery member (30) is offset so as to preferably between 2 to 5 degrees inclined to the longitudinal axis of the delivery member (30), thus, the distal portion of the distal delivery section (31) defines a second different axis of symmetry throughout the passage a first axis of symmetry.

The Gobby device does not disclose the distal passage portion of the delivery section (51) is beveled.

Bacich discloses a transfer catheter body (13) comprising a proximal portion (27), a distal portion (31), an elongated passage (21), the distal portion (31) having an end that is beveled in a first direction across the passage (21) from one side to another, thereby, rendering the bevel in its direction across the opening, as recited, a portion of catheter (13) including a second point beveled in a second direction opposite the first direction defining a tip, showing by $\beta 1$ & $\beta 2$ below. See illustration below.



In view of Bacich, it would have been obvious to one skilled in the art during the time of this invention to modify the Gobby's distal passage portion of the delivery section (51) such that it would have a bevel, as such would facilitate the delivery process.

With regards to claims 1 and 11 reciting the material of the tip, the Bacich reference discloses the catheter body (13) is of polytetrafluoroethylene (PTFE) or other biocompatible, flexible material (column 4 lines 17-20), of which exhibits sufficient rigidity & sufficient flexibility.

With regards to claims 1 and 11 reciting the tip is shaped to be inserted into the endometrial lining of the subject, Figures 4 & 8 in the Bacich reference illustrates the tip of catheter body (13, 13a) is **shaped** to be inserted into the endometrial lining of the subject.

Regarding claims 2 & 3 and 14 & 15, particularly to claims 3 & 15 reciting the beveled opening angled between 10° to 15°, Figure 2 of Bacich illustrates such opening angle range.

Regarding claims 6 & 7 and 12 & 13, particularly to claims 7 & 13 reciting the second axis of symmetry differs by a deflection angle of 10 to 15 degrees from the first axis of symmetry, the Gobby's distal passage portion is deflected or offset from the longitudinal axis preferably by 2 to 5 degrees, however, the 10 to 15 degrees deflection is not out of the ordinary given the anatomy of each women varies from person to person, one skilled in the art during the time of the invention would have modify the Gobby's offset range to be 10 to 15 degrees from the longitudinal axis as such would accommodate various uteral anatomy.

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Furthermore, applicant's specification discloses in paragraph 0028 the preferred deflection 10 to 15 degrees but lacks the criticality for the claimed deflection. Thus, such recited deflection falls within reasonable ranges, one skilled in the art would have considered such deflection ranges for purposes of optimizing the embryo delivery procedure.

With regards to claims 9 & 10 and 17 & 18, particular to claims 10 & 18 reciting the inner diameter of the tip is between approximately 400 and 500 micrometers, the Bacich reference discloses the diameter of the passage (21) is 0.5 millimeter or 500 micrometers, the diameter of the passage (21) is essentially inner diameter of the tip.

With regards to claims 26, 27, and 31, Figure 6 in the Gobby reference illustrates the distal portion of the delivery section (51) is pointed.

With regards to claim 28 & 32, the second point on the catheter body (13) beveling on the second direction (see illustration above) yields a refined edge, thus, serving as a cutting tool.

With regards to claim 29 & 34, Figures 6 in the Gobby reference illustrates the distal portion of the delivery section (51) defines a second different axis of symmetry throughout the passage a first axis of symmetry, rendering that distal portion of member (30) a microsurgical instrument for purposes of inserting into the endometrial lining.

With regards to claim 34, Figure 2 in the Bacich illustrates the angled/beveled distal opening (23) serves as a microsurgical instrument by delivering reproductive biological material (61) reproductive tracts (41).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772